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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,081	07/22/2005	Ole Simonsen	10200.204-US	1176
25908	7590	03/30/2009		
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER	
			DOUYON, LORNA M	
		ART UNIT	PAPER NUMBER	
		1796		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/543,081	<b>Applicant(s)</b> SIMONSEN ET AL.
	<b>Examiner</b> Lorna M. Douyon	<b>Art Unit</b> 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 26 January 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 18-24 and 26-39 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 18-24 and 26-39 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/136/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2009 has been entered.
2. Claims 18-24, 26-39 are pending. Claims 36-39 are newly added.
3. The rejection of claims 18-24, 26, 29-35 under 35 U.S.C. 103(a) as being unpatentable over Izawa et al. (US Patent No. 5,858,952) is withdrawn in view of Applicants' amendment.
4. The rejection of claims 27-28 under 35 U.S.C. 103(a) as being unpatentable over Izawa as applied to the above claims, and further in view of Rahman et al. (US Patent No. 6,355,607) is withdrawn in view of Applicants' amendment.

***Claim Rejections - 35 USC § 112***

5. Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations "at least 51%, 52%, 54% or 56%" in claims 36-39 respectively, are not supported in the specification and are considered as new matter. The added limitations in the claims lack literal basis in the specification as originally filed, see *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem.* 738 F.2d 453 (Fed. Cir. 1984).

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 18-24, 26-27, 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 4,009,076), hereinafter "Green".

Green teaches enzyme granules, particularly for detergent compositions, comprising a granule core of solid material carrying an enzyme and a solid coating of plasticized resin free of the enzyme (see abstract). The carrier material of the core will be of solid non-friable substance suitable for carrying the enzyme like inorganic salts, especially a detergency builder salt, and one example is sodium hexametaphosphate (see col. 2, lines 47-58). The solid material carrying the enzyme can be agglomerated with a cohesive organic material to form a core, and when present, it will usually provide from 2 to 50% by weight of the granule core, and the amount of enzyme will be chosen according to the activity of the enzyme concentrate available (see col. 3, lines 46-53),

the remainder of the granule core will be the amount of the carrier. In Example 1, the carrier (which is granular sodium tripolyphosphate) is present in an amount of about 89% of the granule core ( $81/91.1 \times 100 = 89\%$ ), see col. 5, lines 60-67. The preparation of the granule core can be carried out by conventional methods, for example, an enzyme powder can be mixed with the carrier and a concentrated solution of organic material sprayed on to it and the resulting mass extruded and formed into noodles (see col. 3, line 66 to col. 4, line 5), and thereafter coating the granule core in a Lodige mixer, a pan coater or a drum granulator (see col. 4, lines 6-43). Green also teaches a solid detergent composition comprising enzyme granules as described above (see col. 4, lines 44-47). In Example 8 and 9, Green teaches granule cores which are given a preliminary coating by atomizing on to them in the Lodige mixer a 6.1% solution of anhydrous citric acid in the same ethylene oxide condensate as was present in the slurry (the solution containing 20% citric acid), and the resulting granule cores were further coated with dextrin and glucose (see col. 6, line 49 to col. 7, line 14). It is seen in these examples that the amount of the carrier (i.e., sodium hexametaphosphate in place of sodium tripolyphosphate) in the core is more than 20% of the total amount of the acid (i.e., sodium hexametaphosphate + citric acid) in the granule (as required in claims 22). Green, however, fails to specifically disclose the carrier to be sodium hexametaphosphate in amounts as those recited, and the pH and  $pK_a$  values of the acidic buffer component.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected sodium hexametaphosphate as the carrier

because this is one of the suitable selection of carriers taught by Green and to optimize its proportions within the amounts disclosed for sodium tripolyphosphates as they are used as carrier equivalents because it has been held to be obvious to select a value in a known range by optimization for the best results. As to optimization results, a patent will not be granted based upon the optimization of result effective variables when the optimization is obtained through routine experimentation unless there is a showing of unexpected results which properly rebuts the *prima facie* case of obviousness. See *In re Boesch*, 627 F.2d 272,276,205 USPQ 215,219 (CCPA 1980). See also *In re Woodruff* 919 F.2d 1575, 1578,16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller*, 220 F.2d 454,456,105 USPQ 233,235 (CCPA 1955). With respect to the pH and pK<sub>a</sub> values of the acidic buffer components, i.e., sodium hexametaphosphate in the core, and the citric acid in the preliminary coating, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect the pH and pK<sub>a</sub> values of the acidic buffer components to be within those recited because the same components have been utilized.

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green as applied to the above claims, and further in view of Rahman et al. (US Patent No. 6,355,607), hereinafter "Rahman".

Green teaches the features as described above. Green, however, fails to disclose the acidic buffer component being Na<sub>2</sub>H-citrate.

Rahman, in an analogous art, teaches acids having a builder property such as disodium hydrogen citrate (see col. 2, lines 14-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the builder carrier of Green Izawa with disodium hydrogen citrate because the substitution of one builder for another is within the level of ordinary skill in the art. In addition, the substitution of one builder for another is likely to be obvious when it does no more than yield predictable results.

9. Claims 18-24, 26, 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izawa et al. (US Patent No. 5,858,952), hereinafter "Izawa" in view of Bertacchi et al. (US Patent No. 6,242,407), hereinafter "Bertacchi".

Izawa teaches an enzyme-containing granulated product containing, in a uniformly dispersed state, an enzyme and one or more stabilizers selected from the group consisting of reducing agents and antioxidants; a method for the production of the granulated product, as well as bleaching agents and detergent compositions containing the granulated product (see abstract). Examples of stabilizers include reducing agents, antioxidants, or mixtures thereof, and an example of an antioxidant is ascorbic acid (see col. 2, lines 43-48). The amount of enzymes contained in the granulated product is between 0.01 and 50% by weight (see col. 2, lines 55-62). The amount of stabilizers vary depending on the types of enzymes employed, preferably between 0.1 and 3.000% by weight, more preferably between 1 and 500% by weight, and particularly preferably between 10 and 300% by weight, calculated in relation to the amounts of enzyme

protein (see col. 2, line 62 to col. 3, line 1). Powdery bulking agents may also be added if needed, and one example is sodium citrate (see col. 3, lines 42-52). The method for the manufacture of the granulated product includes spray-drying, freeze-drying, extruding, tumbling, fluidized-bed granulation, spray granulation and disintegration granulation (see col. 3, line 63 to col. 4, line 28). The enzyme-containing granulated product preferably has a coating thereon so as to obtain even further improved stability (see col. 4, lines 33-36). Materials used for coating the enzyme-containing granulated product are not particularly limited, and they may include water-soluble film-forming polymers like polyacrylate (see col. 4, lines 33-43). Coating materials are preferably used in a ratio by weight of 0.1 to 0.7 when the amount of the enzyme-containing granulated product is taken as 1 (see col. 4, lines 47-50). The amount of the enzyme-containing granulated product to be incorporated into a detergent composition is preferably between 0.001 and 70% by weight (see col. 5, lines 6-11). Izawa, however, fails to specifically disclose a core comprising citric acid or adipic acid, the amount of stabilizer within those recited, and the pH and pK<sub>a</sub> values as those recited.

Bertacchi, an analogous art, teaches the equivalency of ascorbic acid with citric acid or adipic acid as antioxidants (see col. 3, lines 45-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the ascorbic acid antioxidant of Izawa with citric acid or adipic acid because the substitution of art recognized equivalents as shown by Bertacchi is within the level of ordinary skill in the art. In addition, the substitution of one

antioxidant for another is likely to be obvious when it does no more than yield predictable results.

With respect to the amount of stabilizer in the core, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the portion of the prior art's range (i.e., between 0.1 and 3,000% by weight in relation to the enzyme) which is within the range of applicants' claims because it has been held to be obvious to select a value in a known range by optimization for the best results. As to optimization results, a patent will not be granted based upon the optimization of result effective variables when the optimization is obtained through routine experimentation unless there is a showing of unexpected results which properly rebuts the *prima facie* case of obviousness. See *In re Boesch*, 627 F.2d 272,276,205 USPQ 215,219 (CCPA 1980). See also *In re Woodruff* 919 F.2d 1575, 1578,16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller*, 220 F.2d 454,456,105 USPQ 233,235 (CCPA 1955). In addition, a *prima facie* case of obviousness exists because the claimed ranges "overlap or lie inside ranges disclosed by the prior art", see *In re Wertheim*, 541 F.2d 257,191 USPQ 90 (CCPA 1976); *In re Woodruff*; 919 F.2d 1575,16USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2131.03 and MPEP 2144.05I.

With respect to the pH and pK<sub>a</sub> values of the citric acid or adipic acid, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect these components to possess a pH and pK<sub>a</sub> values within those recited because similar components have been utilized.

10. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izawa in view of Bertacchi as applied to the above claims, and further in view of Rahman.

Izawa and Bertacchi teach the features as described above. Izawa and Bertacchi, however, fail to disclose  $\text{NaH}_2\text{PO}_4$  or  $\text{Na}_2\text{H-citrate}$ .

Rahman, in an analogous art, teaches the equivalency of citric acid with disodium hydrogen citrate and sodium dihydrogen phosphate as acidification components (see col. 2, lines 14-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the citric acid of Izawa and Bertacchi with disodium hydrogen citrate or sodium dihydrogen phosphate because the substitution of art recognized equivalents as shown by Rahman is within the level of ordinary skill in the art.

#### ***Response to Arguments***

11. Applicant's arguments with respect to the present claims have been considered but are moot in view of the new ground(s) of rejection.

#### **Conclusion**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorna M. Douyon whose telephone number is 571-272-1313. The examiner can normally be reached on Mondays-Fridays 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorna M Douyon/  
Primary Examiner, Art Unit 1796